UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	**ORAL ARGUMENT REQUESTED**

ZHP DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO SEAL

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Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare U.S., LLC (collectively, the "ZHP Defendants") respectfully submit this Memorandum of Law in support of their Motion To Seal specific portions of the Expert Report of Fengtian Xue, Ph.D. dated December 22, 2022 (the "Xue Report"), which was previously filed *in camera* by Plaintiffs in connection with their motion to exclude Dr. Xue's opinions. (*See* Ex. 2 to Pls.' Br. in Supp. of *Daubert* Mot. to Preclude Ops. of Defense Expert Fengtian Xue, Ph.D. at ECF No. 2288-3 (redacted version attached to the Certification of Jessica Davidson, Esq. ("Davidson Cert.") as Ex. 1).)[1] The Xue Report was properly designated as "confidential" pursuant to the Court's Confidentiality Order (ECF No. 1661) because it contains sensitive, confidential and proprietary information about the manufacturing and testing processes and practices utilized by ZHP in manufacturing valsartan active pharmaceutical ingredient ("API"). This includes information contained in the drug master files ("DMFs") ZHP submitted to the FDA, which contain highly-detailed technical information about the API manufacturing and testing process – and are viewed as highly

[1] A detailed index of the material in the Xue Report that ZHP seeks to seal is included in the Certification of Christopher Cox ("Cox Cert."), dated July 20, 2023 (attached to Davidson Cert. as Ex. 2), consistent with Local Civil Rule 5.3. Further support for ZHP's confidentiality claims with respect to this document is included in the Declaration of Jucai Ge in Support of ZHP Defendants' Motion to Seal ("Ge Decl."), dated July 20, 2023 (attached to Davidson Cert. as Ex. 3).

confidential by the FDA and within the pharmaceutical industry. As set forth below, disclosure of such information would cause serious and unjustified injury to the competitive standing of ZHP. Accordingly, the ZHP Defendants respectfully request that the Court permit the redaction of confidential information from the Xue Report.

FACTUAL BACKGROUND

Plaintiffs assert a variety of claims on behalf of multiple subclasses of third-party payers ("TPPs") in certain states who paid any amount of money for a valsartan-containing drug ("VCD") that includes valsartan API manufactured by ZHP. Discovery in this case involved the production of a wide range of confidential and proprietary information belonging to ZHP, including, *inter alia*, information related to the manufacturing processes ZHP used to produce the valsartan API at issue (such as information from the DMFs ZHP submitted to the FDA) and ZHP's investigations regarding the root cause of the nitrosamine contamination discovered in its valsartan API.

This Court has entered an Amended Confidentiality and Protective Order governing the treatment of confidential information, which provides that the parties have the right to designate certain documents "CONFIDENTIAL INFORMATION," including those that contain, among other things, "proprietary, trade secret and/or highly sensitive commercial information," "trade secrets,"

"research, technical, commercial or financial information that has been maintained as confidential," or "other non-public sensitive or proprietary information." (ECF No. 1661, at 4 ("Confidentiality Order").) The Confidentiality Order also provides that the parties and non-parties have the right to designate certain documents "RESTRICTED CONFIDENTIAL INFORMATION," including those that "contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including proprietary manufacturing and production information (including formulation); . . . trade secrets; . . . [and] other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm." (*Id*. at 6-7.) Dr. Xue signed and complied with the Confidentiality Order and protected the materials used in his report in accordance with it. (Confidentiality Order Signed by Dr. Fengtian Xue (Nov. 20, 2022), attached to Davidson Cert. as Ex. 4.)

Pursuant to the Confidentiality Order, confidential discovery material (including documents designated "Confidential" or "Restricted Confidential") should be "filed under seal in accordance with Local Rule 5.3." (*Id*. at 21.) On March 13, 2023, Plaintiffs filed their *Daubert* Motion to Preclude Opinions of Defense Expert Fengtian Xue, Ph.D. (*See* ECF No. 2288.) Certain exhibits to that motion, including the Xue Report, which was marked "Confidential" pursuant to the

Confidentiality Order,[2] were submitted as slip sheets and provided to the Court directly via email for its *in camera* review, consistent with the Confidentiality Order. (*See* ECF No. 2288-3.) The ZHP Defendants now seek to file a redacted version of the Xue Report on the docket that does not include information designated as confidential. (*See* Cox Cert. ¶¶ 3-6.)

ARGUMENT

While "there exists 'a common law public right of access to judicial proceedings and records,'" courts have recognized that "[t]his right of access is not absolute . . . and must be balanced against countervailing interests in secrecy." *Nexus Pharms., Inc. v. Nevakar, Inc.*, No. 22-5683 (RMB/SAK), 2023 WL 3338317, at *1 (D.N.J. May 10, 2023) (citations omitted). The right to public access may be overcome where a party "demonstrat[es] that 'good cause' exists for the protection of the material at issue" based on a "showing that disclosure will work a clearly defined and serious injury to the party seeking closure." *Fields PAG, Inc. v. CDK Glob., LLC*, No. 16-cv-01876-MCA-MAH, 2016 WL 9185293, at *2 (D.N.J. June 10, 2016) (citations omitted). Consistent with Local Civil Rule 5.3(c)(3), courts considering requests to seal confidential materials should consider: "(a) the nature

[2] While the Xue Report was marked "Confidential," other documents that contain the same or similar information contained in the Xue Report were marked as "Restricted Confidential." (*See* Cox Cert. ¶ 4.)

of the materials or proceedings at issue, (b) the legitimate private or public interests which warrant the relief sought, (c) the clearly defined and serious injury that would result if the relief sought is not granted, and (d) why a less restrictive alternative to the relief sought is not available." *Briglia v. Ameritas Life Ins. Corp*., No. 1:14-CV-07968-RBK-KMW, 2015 WL 4314062, at *2 (D.N.J. July 14, 2015). In addition, courts in the District of New Jersey have noted that where, as here, the parties have agreed to a confidentiality order, this agreement weighs in favor of maintaining under seal those documents properly subject to the order. *See Goldenberg v. Indel, Inc.*, No. 09-5202 (JBS/AMD), 2012 WL 15909, at *2 (D.N.J. Jan. 3, 2012) (granting motion to seal and noting that any "argument that th[e] documents are not confidential and that disclosure would not cause . . . clearly defined and serious injury is questionable in light of the [p]laintiffs' previous acknowledgment of these categories of confidentiality in the joint [d]iscovery [c]onfidentiality [o]rder").

As set forth below – and in the Cox Certification and Ge Declaration attached hereto – there is good cause to seal the redacted portions of the Xue Report because public disclosure of the information contained therein would reveal to ZHP's competitors sensitive, confidential and proprietary information about the manufacturing and testing processes and results utilized by ZHP, thereby causing ZHP distinct competitive harm. By contrast, there is little, if any, public interest in making this highly technical information generally available, especially given that a

wealth of information related to Plaintiffs' allegations is already available to the public. Finally, the relief the ZHP defendants request – i.e., redaction of limited portions of the Xue Report – is the least restrictive approach necessary to protect the confidential nature of the materials at issue.

I. GOOD CAUSE EXISTS TO REDACT CONFIDENTIAL PORTIONS OF THE XUE REPORT.

The Court should grant the ZHP defendants' motion to seal in light of ZHP's significant interest in maintaining confidentiality with respect to its sensitive, confidential and proprietary information related to its manufacturing processes. Specifically, and as detailed in the Cox Certification and Ge Declaration, the Xue Report includes non-public trade secret information that is closely guarded by ZHP and the disclosure of which could cause real tangible harm to ZHP. This includes detailed technical information regarding ZHP's manufacturing and testing processes for valsartan API included in ZHP's confidential DMF filing with the FDA. (*See* Cox Cert. ¶¶ 4-6; Ge Decl. ¶ 5.)

"The Third Circuit, as well as [courts in this district], ha[ve] recognized on numerous occasions that confidential and sensitive business information is the type of information that should be protected from public disclosure." *Valeant Pharms. Luxembourg S.a.r.l. v. Actavis Lab'ys UT, Inc.*, No. 16-04344(JLL)(JAD), 2018 WL 1832914, at *3 (D.N.J. Apr. 16, 2018); *see also Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984) (the "protection of a party's interest in confidential

commercial information" is an exception to the right of public access); *see also Impax Lab'ys, Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:17-13476 (SRC) (CLW), 2018 WL 10151204, at *3 (D.N.J. Nov. 27, 2018) (protecting from public view "confidential research and development, product testing, formulations, and other trade secret information"); *Otsuka Pharm. Co. v. Aurobindo Pharma Ltd.*, No. 14-3306-JBS-KMW, 2016 WL 11645538, at *2 (D.N.J. Oct. 24, 2016*)* (granting motions to seal where "the parties seek to seal confidential, trade secrets and/or proprietary business information which the parties have designated confidential pursuant to the [d]iscovery [c]onfidentiality [o]rder entered in this case").

"In particular, this [c]ourt has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, ***drug master files***, formulations, and other confidential testing by drug manufacturers." *Amgen Inc. v. Zydus Pharms. (USA) Inc.*, No. 19-18806(MAS)(DEA), 2021 WL 2550449, at *2 (D.N.J. May 18, 2021) (emphasis added). Indeed, both the FDA and courts have recognized that information contained in a DMF – which makes up a significant portion of the information the ZHP Defendants seek to redact from the Xue Report (*see generally* Cox Cert. and Ge Decl.) – is inherently confidential and therefore not subject to public disclosure. For example, 21 C.F.R. § 314.430, provides that "data and information" regarding "[m]anufacturing methods or processes, including

quality control procedures," that are included in a DMF are immune from public disclosure by the FDA. The reason for this rule is clear: disclosure of this information would cause a clearly defined and serious injury to a DMF applicant by allowing its competitors an unfair look into the applicant's proprietary manufacturing methods and testing practices. This creates the serious risk that competitors will use an applicant's DMF information to advance their own business interests, including by using the information to develop and test competing products, putting the applicant at a distinct and unfair competitive disadvantage. Consistent with the FDA's approach, courts have refused to order public disclosure of DMF materials in connection with litigation due to confidentiality concerns. *See, e.g.*, *In re Gabapentin Pat. Litig.*, 312 F. Supp. 2d 653, 660, 667, 669 (D.N.J. 2004) (affirming magistrate judge's refusal to unseal materials, including information from defendants' DMF, noting that the "FDA is specifically prohibited from disclosing" such information).

Courts also regularly protect from disclosure other FDA filings that contain manufacturing and test information similar to that set forth in a DMF, such as Abbreviated New Drug Applications ("ANDAs") filed by finished-dose pharmaceutical manufacturers, for similar reasons. *See Valeant*, 2018 WL 1832914, at *2 (granting motion to seal "proprietary commercial and business interests, including information relevant to [d]efendant's research, development, and technical

information on the components and formulation of its ANDA product, which is presently unavailable to the public"); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharms. Inc.*, No. 14-4727 (NLH/KMW), 2015 WL 4715307, at *1-2 (D.N.J. Aug. 7, 2015) (granting motion to seal portions of documents containing "highly proprietary business information regarding the development, formulation, manufacture and sales of [Mylan's] ANDA products"). Consistent with these rulings, courts in this District have also generally held that "confidential" information regarding "proprietary manufacturing processes" and testing is immune from production. *Immunomedics, Inc. v. Roger Williams Med. Ctr.*, No. 15-4526 (JLL) (SCM), 2016 WL 10572644, at *1-2 (D.N.J. Dec. 22, 2016) (sealing information contained in "material transfer agreements" regarding certain biomedical research materials given "the [p]arties will suffer injury and/or competitive harm if the information set forth in the MTAs and the substance thereof . . . is, in fact, publicly-disclosed"); *see also Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571-MLC-TJB, 2017 WL 27460, at *1-2 (D.N.J. Jan. 3, 2017) (sealing confidential manufacturing and research and development processes and information in third-party laboratory notebooks); *Purdue Pharm. Prods. L.P. v. Actavis Elizabeth LLC*, No. 12-CV-05311 (JLL)(JAD), 2015 WL 13691888, at *1 (D.N.J. Aug. 24, 2015) (granting motion to seal portions of trial transcript that related to "the formulation of [an] ANDA product and bioequivalence testing data").

The same result is appropriate here. As explained in the attached declaration of Jucai Ge, Executive Vice General Manager of Hubei Saiao Biopharmaceutical Co., Ltd., a subsidiary of ZHP, the redacted portions of the Xue Report contain "highly sensitive and detailed information regarding ZHP's manufacturing of Valsartan [API] . . . including information regarding ZHP's ***current manufacturing processes***." (Ge Decl. ¶¶ 1, 5.) Among other things, the redactions cover information contained in the DMFs submitted by ZHP to the FDA, "which is closely guarded by ZHP and considered among the most confidential and sensitive information in the company." (*Id.*) As a result, "[p]ublic disclosure of the Redacted Information would result in significant commercial harm to ZHP by revealing to its competitors detailed information regarding its manufacturing processes, including its ***current manufacturing processes***." (*Id.* ¶ 6.) Specifically, such information includes: "(a) the materials it uses in specific steps, (b) the quantities or amounts of such materials, and perhaps most significantly, (c) the company's rationale for those process decisions." (*Id.*) For example, the Xue Report "delineates how the company changed a number of specific steps in its manufacturing process and why." (*Id.* ¶ 7.) This information could be easily "exploited commercially by ZHP's competitors." (*Id.*) Similarly, other portions of the Xue Report contain "detailed technical know-how relating to ZHP's manufacturing processes" and "details regarding ZHP's testing for impurities, including whether the evaluations were affected by the process

changes" that are at issue in this litigation. (*Id.* ¶¶ 9-10.) Both categories of information could be easily adapted and used by ZHP's competitors to ZHP's detriment. (*Id.*) Thus, the public disclosure of any of the information tentatively redacted in the Xue Report "would cause serious competitive harm to ZHP." (*Id.* ¶ 11.)

In short, the detailed, technical manufacturing and testing information ZHP seeks to redact from the Xue Report is highly confidential and its release would cause a "clearly defined and serious injury" to ZHP's competitive standing. *Immunomedics, Inc.*, 2016 WL 10572644, at *1. As a result, there is good cause to grant the ZHP Defendants' motion to seal.

II. ZHP'S SIGNIFICANT INTEREST IN MAINTAINING THE CONFIDENTIALITY OF THE INFORMATION IN THE XUE REPORT OUTWEIGHS ANY LIMITED PUBLIC INTEREST IN DISCLOSURE.

The ZHP Defendants' motion to seal should also be granted because ZHP's significant interest in protecting the information contained in the redacted portions of the Xue Report outweighs any potential public interest in disclosure of that material.

Courts have recognized that a litigation defendant's legitimate business interest in preventing its competitors from being "able to unfairly use [the defendant's] otherwise confidential and proprietary business information to their competitive advantage," can outweigh any public interest in disclosure. *Everest*

Nat'l Ins. Co. v. Sutton, No. 07-722 (JAP), 2010 WL 4387522, at *3, *6-7 (D.N.J. Oct. 28, 2010); *see also Fields*, 2016 WL 9185293, at *2 (where a "case involves private litigants, and concerns matters of little legitimate public interest" this weighs "in favor of granting or maintaining an order of confidentiality") (citation omitted).

Here, ZHP has a significant interest in preventing the competitive injuries that would result from the disclosure of the portions of the Xue Report at issue for all the reasons set forth in Section I, above, and this interest far outweighs any possible benefit of public disclosure. The general public has very limited – if any – interest in access to proprietary, technical information about the manufacturing and testing processes used by ZHP in manufacturing valsartan API. While Plaintiffs may argue that the material is relevant to a public health issue because recalled valsartan API and VCDs contained nitrosamines, the information the ZHP Defendants seek to protect is highly technical and therefore the general public will have little, if any use for it. *See, e.g.*, *In re Incretin-Based Therapies Prods. Liab. Litig.*, No. 13md2452 AJB (MDD), 2021 WL 873290, at *3 (S.D. Cal. Mar. 9, 2021) ("[T]he [c]ourt finds the threat of competitive harm from disclosure and the potential to confuse and mislead the public about sitagliptin's safety profile outweigh the public's right of access and amount to compelling reasons to maintain the information at issue under seal.").

In addition, there are copious materials related to Plaintiffs' allegations available in the public domain – including detailed public statements by the FDA about the VCD recalls and the agency's subsequent investigations regarding the presence of nitrosamines in certain VCDs. Further, the FDA, which is tasked with protecting the public health with respect to prescription drugs, already has the information at issue from ZHP's various DMF filings and other submissions to the agency. As a result, there is no significant public interest implicated by the limited redaction of portions of the Xue Report.

III. THE ZHP DEFENDANTS HAVE PROPOSED THE LEAST RESTRICTIVE APPROACH.

Finally, the ZHP Defendants have adopted the least restrictive approach necessary to protect the confidentiality of the material at issue. The ZHP Defendants do not seek to seal the entirety of the Xue Report, but instead propose only limited redactions to 13 of the 58 pages in the Xue Report to remove confidential, technical information about ZHP's manufacturing and testing processes. (*See* Cox Cert. ¶¶ 5-6.) Accordingly, the ZHP Defendants' proposed approach is narrowly tailored, and provides the least restrictive means for protecting ZHP's confidential business information from disclosure. *See Immunomedics, Inc.*, 2016 WL 10572644, at *2 ("Sealing only the portions requested is the least restrictive means to protect the information because redacted versions are publicly-filed."); *Costa v. County of Burlington*, No. 07-904 (JEI), 2010 WL 11566091, at *2 (D.N.J. July 7, 2010)

("Finally, by redacting the documents—as opposed to sealing the exhibits wholesale—Costa has used the least restrictive means available.").

CONCLUSION

For all of the reasons set forth above, the ZHP Defendants respectfully request that the Court grant their Motion to Seal.

Dated: July 20, 2023

Respectfully submitted,

By: */s/ Jessica Davidson*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 20, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
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